# **Drugs for Alzheimer's Disease**

# Key Questions and Inclusion Criteria

## Update #1

# **Key Questions**

- 1. How do the included drugs or drug combinations (i.e., acetylcholinesterase inhibitor plus memantine) compare in their effectiveness for stabilizing symptoms and treating behavioral disturbances in patients with Alzheimer's Disease?
- 2. How do these drugs or drug combinations compare in their time to effect and in the time required to assess the clinical response?
- 3. What are the comparative incidence and severity of complications of these drugs or drug combinations?
- 4. Do the included drugs or drug combinations differ in effectiveness or adverse events in the following subgroups:
  - different racial groups, genders, or age groups?
  - •patients with Parkinsonian features or vascular dementia?
  - patients taking other commonly prescribed drugs?

#### **Inclusion Criteria**

#### Population

- Specific subpopulations will include patients
  - with mild (early-stage) Alzheimer's Disease
  - with moderate to severe (mid- to late-stage) Alzheimer's Disease
- Patients living at home or in skilled nursing facilities

#### Interventions

Generic Name		Trade Name
Acetylcholinesterase	Donepezil hydrochloride	Aricept
Inhibitors	Rivastigmine tartrate	Exelon
	Galantamine	Razadyne
	Galantamine ER	Razadyne ER
	Tacrine	Cognex
NMDA Receptor	Memantine	Namenda
Antagonists		

#### Effectiveness outcomes

- Mortality
- •Stabilizing or slowing the rate of decline in:
  - Day-to-day function (e.g., activities of daily living, instrumental activities of daily living, level of care changes)
  - Cognition
  - Quality of life
- Reducing behavioral symptoms (e.g., aggression, agitation, psychosis, mood disorders)
- Decreasing caregiver burden
- Reducing hospitalizations or nursing home placement

### Safety outcomes

- Overall adverse effects
- · Withdrawals due to adverse effects
- · Serious adverse events reported
- Adverse events due to discontinuation (temporary or permanent)
- Specific adverse events (e.g., hepatotoxicity, weight loss, gastrointestinal symptoms, other specific adverse events)

## Study designs

- For effectiveness, controlled clinical trials and good-quality systematic reviews.
- For safety, in addition to controlled clinical trials, observational studies will be included.